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PLEASE DELIVER THE FOLLOWING PAGE(S) TO:

NAME:	Examiner Kevin C. Simpons		
FIRM:	USPTO		
CITY:	Arlington, VA	DATE:	January 14, 2002
TELEPHONE NO.:	(703) 306-5410		
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MESSAGE:

Copy #19

Docket No. 5637.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

October 25, 2001
Date

October 25, 2001

RESPONSE TO OFFICE ACTION

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicants respectfully request reconsideration of the rejection of claims 2-7, 10-12, and 26-28, mailed on June 27, 2001. The applicants respectfully request, in particular, that the Examiner reconsider the assertion that the cartridge holder element 300 of the cited Chanoch patent can be deemed to be part of a

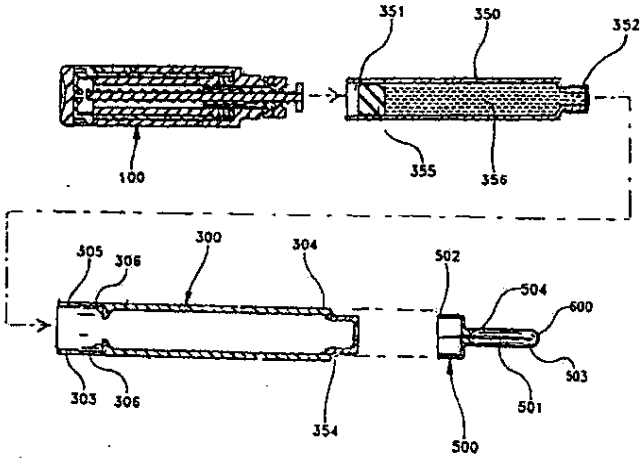
"molded cartridge" element as recited in claim 26. In requesting reconsideration, the applicants note that the Examiner's position that the cartridge holder 300 of Chanoch can be deemed to be part of a "molded cartridge" as recited in claim 26 is inconsistent with the Examiner's interpretation of DiBiasi U.S. patent No. 6,146,361, set forth in the final rejection dated January 17, 2001. In previously applying DiBiasi to claim 26, the Examiner asserted that the element in DiBiasi corresponding to the "molded cartridge" in claim 26 constitutes the cartridge 22 only, and not the cartridge holder.

Claim 26 claims a "cartridge assembly" that includes a "molded cartridge" with a stopper. Claim 26 further requires that the "cartridge assembly" includes two coupling means for engaging, respectively, a needle assembly and the dosing assembly. Finally, claim 26 recites that "at least one of said coupling means is unitarily molded with the **cartridge**" (i.e., at least one of the coupling means must be unitarily molded with the cartridge, and not merely associated with the cartridge assembly).

Chanoch U.S. patent No. 5,688,251 discloses a pen type syringe which includes a "cartridge holder assembly 300" that includes "a molded housing 304." Col. 5, lines 50-51. A "medication cartridge 350 [is] securely retained in housing 304." Col. 6, lines 1-2. More particularly, a "cap 354 extends between housing 304 and cartridge 350 for securely and permanently holding medication cartridge in housing 304." Col. 6, lines 3-8. Finally, a needle cannula assembly 500

has a mounting hub 504 which is "threadingly engageable with the cap 354." Col. 6, lines 15-20.

The disclosure that, but for the cap 354, the cartridge 350 can be separated from the cartridge holder housing 304 means that the housing 304 and cartridge 305 are separate elements, which are mechanically coupled to one another during some stage of the assembly process. Thus, if Fig. 2 of Chanoch were modified to show the parts of the syringe prior to such assembly, it would be as follows:



Thus, as evident from the Chanoch specification, the cartridge holder 300 is not molded unitarily with the cartridge 350 - they are separate elements.

As discussed above, claim 26 recites two coupling means for engaging, respectively, a needle assembly and the dosing assembly, and recites that "at

least one of said coupling means is unitarily molded with the [molded] cartridge." Chanoch discloses two coupling means: (1) internal threads 303 formed in the barrel of the cartridge holder 300 (which engage cooperating threads on the pen body 100), Col. 5, lines 55-57; and (2) threads on the external surface of the cap 354 (which engage internal threads provided in the needle hub 504). Col. 6, lines 18-20. Thus, Chanoch disclose two coupling means for engaging, respectively, a needle assembly and a dosing assembly. However, in Chanoch both such coupling means are provided on the cartridge holder, not on the "molded cartridge" itself. Thus, Chanoch does not anticipate or suggest claim 26.

The commonly owned Chanoch and DiBiasi patents both show a syringe having a cartridge holder element which screws onto a pen body. Both the cartridge holder of Chanoch and the cartridge holder of DiBiasi receive a separate cartridge. The difference between Chanoch and DiBiasi is that, in Chanoch, once the cartridge is inserted in the cartridge holder barrel, it cannot be removed. Thus, when the cartridge is empty, the user must replace both the cartridge and the cartridge holder. In contrast, DiBiasi allows the cartridge to be removed from the cartridge holder when empty, so that only the cartridge, and not the cartridge holder needs to be replaced. This difference is immaterial relative to the claims of the present application.

As discussed in the applicants's Response After Final Rejection dated June 11, 2001, in applying DiBiasi to claim 26, the Examiner did not consider the

cartridge holder to be part of the claimed "molded cartridge." Rather, the Examiner deemed the cartridge 22 of DiBiasi to correspond to the "molded cartridge" of claim 26, and treated the "cartridge retainer" 10 of DiBiasi to constitute a separate element. Final Office Action, Paragraph 2.

The cartridge holder and cartridge shown in DiBiasi are very similar to the cartridge holder and cartridge shown in Chanoch, except that, in Chanoch, the cartridge is permanently retained in the cartridge holder (and insofar as the cartridge holder barrel in Chanoch has internal threads to engage the pen body). Thus, it is inconsistent for the Examiner to deem the cartridge (but not the cartridge holder) to constitute a "molded cartridge" when interpreting DiBiasi, and yet to deem both the cartridge and the cartridge holder to constitute a "molded cartridge" when interpreting Chanoch.

For such reason, the applicants do not believe that the combination of the cartridge 350 and the cartridge holder 300 of Chanoch can properly be deemed to correspond to a "molded cartridge." Certainly, a person skilled in the art would not deem a cartridge holder to be part of a molded cartridge, as evidenced by the fact that the Chanoch specification clearly differentiates between a cartridge and a cartridge holder. *See, Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578, 38 U.S.P.Q.2d 1126, 1129 (Fed. Cir. 1996) (stating that a claim term is to be given the meaning that it would be given by persons experienced in the field of invention).

Because the rejection of the claims hinges on the assertion that the cartridge holder 300 of Chanoch is part of a "molded cartridge," the applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

Robert B. Smith

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 735-3020

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

26137 7590 04/30/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 04/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/348,536	BUCH-RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Kevin C. Simons	3763	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,10-12 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 7, 10-12 and 26-28* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01) Office Action Summary Part of Paper No. 20

DETAILED ACTION

Claim Rejections - 35 USC § 102

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

II. Claims 26-28, 2-4, 6, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device comprising: a cartridge assembly (300&350) having opposite ends, and a dosing assembly (100), wherein said cartridge assembly includes a molded cartridge (300&350) and a stopper disposed in said cartridge (306), wherein one end (distal end of 300&350) of said cartridge assembly is sealed with a pierceable sealing (353), wherein said one end includes a first coupling means (see fig. 4) for releasably mounting a needle assembly having a skin-piercing needle (501), and wherein the other end of said cartridge assembly includes a second coupling means (303) for engaging said dosing assembly (100), wherein at least one of said coupling means is unitarily molded with the cartridge (since 300&350 in combination are the cartridge, then, 303 represents the coupling means on the distal and proximal end of the cartridge), and wherein said dosing assembly includes a housing (101), plunger (fig. 4), and a mechanism for setting a desired dose and for moving said plunger (fig. 2&3), relative to said housing in an axial direction for administering a set dose (functional language), (figs. 2&3),

and wherein said dosing assembly housing includes a coupling member (fig. 2&3) for engaging said second coupling means of said cartridge assembly (figs. 2&3); for securing said housing against axial movement relative to said cartridge assembly (figs. 2&3) and such that said plunger engages said stopper for moving said stopper in response to plunger movement (figs. 2&3); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 3 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (fig. 4); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (figs. 2&3); the coupling of the cartridge assembly are opposed (figs. 3 and 2); wherein the said at least one coupling means is said second coupling means (figs. 3 and 2); wherein said second coupling means is a threaded coupling (figs. 3 and 2); a dosing assembly with a scale (col. 5, lines 1-10); wherein the cartridge is molded of a plastic material (fig.2 and 3).

Claim Rejections - 35 USC § 103

III. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

IV. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device substantially as claimed except for: wherein the cartridge is at least partly transparent (figs. 3 and 2). However, Chanoch discloses that the cartridge is made of plastic. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plastic cartridge of Chanoch since it well known that plastics can be made transparent.

Response to Arguments

Applicant's arguments filed 1/14/02 have been fully considered but they are not persuasive.

Note: the examiner will address argument only directed to the current art rejection.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "at least one of said coupling means is unitarily molded with the cartridge") (i.e., at least one if the coupling means must be unitarily molded with the cartridge, and not merely associated with the cartridge assembly). Simply, applicant discloses a cartridge assembly (1) and a cartridge (5) which both characters "1" and "5" have been used to designate one specific part clearly shown in (fig. 3). Chanoch clearly discloses a cartridge assembly (300 & 350) and a cartridge (300 & 350) which have been used to designate one specific part shown in (figs. 2-4). The cartridge assembly and cartridge are secured together. Evidently they are not separable! Basically, they are considered to be a whole, one unit.

V. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons

Patent Examiner
4/25/02

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

AF/376

#21

Attorney Docket No.: 5637.200-US

PATENT

(N.E. Bruce)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3763

Filed: July 30, 2002 Examiner: To be assigned

Confirmation No: 5366

Please Enter KCS 9/17/02

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Amendment and Response After Final Rejection

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on July 30, 2002.

Maya Faison-Phillip
(name of person mailing paper)

Maya Faison-Phillip
(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/348,536

Group Art Unit: 3763

Filed: July 30, 2002

Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

AMENDMENT AND RESPONSE AFTER FINAL REJECTION

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed 4/30/02, applicants respectfully request entry of the following amendment and remarks, and reconsideration of the final rejection of the pending claims. Accordingly, please amend the above-captioned application as follows:

IN THE CLAIMS:

Please cancel claim 5 without prejudice or disclaimer.

Please add new claim 29:

29. (New) A medication delivery device comprising a cartridge assembly having opposite ends and a dosing assembly for setting a desired dose and acting on the cartridge assembly to cause the desired dose to be delivered, wherein:

the cartridge assembly includes a molded cartridge and a stopper disposed in the cartridge, wherein one end of the cartridge assembly is sealed with a pierceable sealing, wherein the one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle, and wherein the other end of the cartridge assembly includes a second coupling means for engaging the dosing assembly, wherein at least one of the coupling means is unitarily molded with the cartridge, and wherein the dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving the plunger relative to the housing in an axial direction for administering a set dose, and wherein the dosing assembly housing includes a coupling member for engaging the second coupling means of the cartridge assembly for securing the housing against axial movement relative to the cartridge assembly such that the plunger engages the stopper for moving the stopper in response to the plunger movement wherein the at least one coupling means of the cartridge assembly is a threaded coupling and wherein the second coupling means is an external threaded coupling.

REMARKS

Claim 5 has been canceled without prejudice or disclaimer. New claim 29 is an independent version of cancelled claim 5 and includes all the limitation of the base claim and any intervening claims upon which claim 5 depended.

It is respectfully submitted that the present amendment presents no new issues or new matter and places claim 29 in condition for allowance, thus reducing issues on appeal, should an appeal become necessary.

In the previous office action, the Examiner finally rejected all pending claims, except for claim 5, under 35 USC 102(e) in view of U.S. Patent No. 5,699,251 to Chanoch. Applicants respectfully request reconsideration in view of the following remarks.

Applicants respectfully disagree with the Examiners assertion in the previous office action that the Chanoch device operates with a cartridge assembly in a similar manner to the applicants invention as defined by the pending claims. While Chanoch might be viewed as showing a cartridge holder assembly comprising a cartridge and coupling means for mounting a dose setting part and for mounting an injection needle, applicants' invention as defined by the claims requires explicitly that at least one of the coupling means is unitarily molded with the cartridge. This feature is not found in Chanoch.

At best, Chanoch discloses that the cartridge holder assembly 300 is a unit comprising parts such as a housing 304, a cartridge 350, and coupling means 305 for coupling a pen body assembly to the cartridge holder assembly 300 and coupling means 303 for coupling an injection needle to the cartridge holder assembly. However, none of these coupling means 305 or 303 are unitarily molded with the cartridge 350 but are merely provided on the housing 304.

In the embodiment shown in figure 3 in the instant application the cartridge 5 is provided with both the mentioned coupling means 2 and 3 for coupling to the needle and to the pen body assembly, respectively. In this embodiment the cartridge 5 with its couplings 2 and 3 forms a cartridge assembly 1. This cartridge assembly 1 is molded as one integral part. In contrast Chanoch discloses that the cartridge holder assembly 300 comprises the cartridge 350 but the coupling means 305 and 303 are unitary molded with the housing 304, not with the cartridge 350.

Applicants respectfully disagree with any assertion that tries to equate the cartridge assembly 300 with the cartridge 350. Reference numeral 300 in Chanoch designates a collection of single elements of which the cartridge 350 is one. In contrast, applicants' figure 3 shows clearly that the cartridge 5 is one integral part which is provided with coupling means 2 and 3 to appear as a cartridge assembly 1. If only one of the coupling means had been provided for in applicants' molded cartridge, applicants cartridge assembly could have been constructed like the one shown by Chanoch with a cartridge holder assembly comprising a housing accommodating a cartridge and carrying the coupling means which were not provided on the cartridge, but even with this construction the device according to applicants' invention as claimed would differ from the Chanoch construction because at least one of the coupling means is unitarily molded with the cartridge.

As evidence that the reference numbers 1 and 300 designate assemblies and not single parts applicants point out that Chanoch's reference lines are provided with an arrow widely pointing at the assembly referred to. Elsewhere, Chanoch used other reference lines that each lead to a single part or feature.

In sum, applicants respectfully note that Chanoch's cartridge holder assembly 300 only superficially appears like applicants' cartridge assembly as claimed but, upon a detailed review, the construction of the two assemblies differs.

Channoch's assembly is built from at least two parts: a housing carrying coupling means and a common cartridge. In contrast, applicants' invention as defined by the claims requires that in the assembly the cartridge is special as it carries at least one of the coupling means. A housing may be provided carrying the other coupling means, or the assembly may be made as one integral part as the one shown in figure 3, but still at least one coupling means is unitarily molded with the cartridge.

CONCLUSION

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Applicants respectfully request withdrawal of the final rejection and reconsideration and allowance of the pending claims. The Examiner is hereby invited to contact the attorney for the applicants by telephone if there are any questions concerning this amendment or application. Should any fee be due in connection with this paper or this application, the Commissioner is hereby authorized to charge any fee to Deposit Account No. 14-1447.

Respectfully submitted,

Date: July 30, 2002

Marc A. Began, Reg. No. 48,829
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405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
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23650
PATENT TRADEMARK OFFICE

M

Notice of Allowability	Application No. 09/348,536	Applicant(s) BUCH-RASMUSSEN ET AL.
	Examiner Kevin C. Simmons	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/20/01.
2. ☒ The allowed claim(s) is/are 2,3,6,7,10,11 and 29.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received. Certified Copy @ PTO.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☒ CORRECTED DRAWINGS must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☒ to Paper No. 8.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No. ____.
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6☒ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marc A. Began on 9/10/02.

The application has been amended as follows:

Please cancel claims 4 and 26-28.

In claim 2, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 3, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 6, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 10, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 12, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 703-306-5410. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0000.

KCS

Kevin C. Sirmons
Patent Examiner
September 17, 2002

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	**CLASS-SUBCLASS**
3763	604-232000

DATE MAILED: 09/20/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

TITLE OF INVENTION: MEDICATION DELIVERY DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1280	$0	$1280	12/20/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE
Commissioner for Patents
Washington, D.C. 20231
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.100-US	5366

TITLE OF INVENTION: MEDICATION DELIVERY DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1280	$0	$1280	12/20/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIMMONS, KEVIN C	3763	604-232000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 09/20/2002

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

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United States Patent and Trademark Office
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26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 09/20/2002

Notice of Possible Fee Increase on October 1, 2002

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2002, then the amount due may be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there may be an increase in fees effective on October 1, 2002. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Notice of Proposed Rulemaking, 67 Fed. Reg. 30634, 30636 (May 7, 2002). Although a change to the amount of the publication fee is not currently proposed for October 2002, if the issue fee or publication fee is to be paid on or after October 1, 2002, applicant should check the USPTO web site for the current fees before submitting the payment. The USPTO Internet address for the fee schedule is: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of any fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after October 1, 2002 (or mailed with a certificate of mailing on or after October 1, 2002), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

Form PTO-948 (Rev. 8-93) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 348536

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 7/7/98 are:

A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be submitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ___ Color drawings are not acceptable until petition is granted. Fig(s) _____
   - ___ Pencil and non black ink not permitted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84 (b)
   - ___ 1 full-tone set is required. Fig(s) _____
   - ___ Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s) _____
   - ___ Poor quality (half-tone). Fig(s) _____
3. TYPE OF PAPER. 37 CFR 1.84(e)
   - ___ Paper not flexible, strong, white, and durable. Fig(s) _____
   - ___ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) _____
   - ___ Mylar, velum paper is not acceptable (too thin). Fig(s) _____
4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   - ___ 21.0 cm by 29.7 cm (DIN size A4)
   - ___ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - ___ All drawing sheets not the same size. Sheet(s) _____
   - ___ Drawings sheets not an acceptable size. Fig(s) _____
5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

   Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm
   SIZE: A4 Size

   Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm
   SIZE: 8 1/2 x 11

   Margins not acceptable. Fig(s) _____
   - _____ Top (T) _____ Left (L)
   - _____ Right (R) _____ Bottom (B)
6. VIEWS. 37 CFR 1.84(h)
   REMINDER: Specification may require revision to correspond to drawing changes.
   Partial views. 37 CFR 1.84(h)(2)
   - ___ Brackets needed to show figure as one entity. Fig(s) _____
   - ___ Views not labeled separately or properly. Fig(s) _____
   - ___ Enlarged view not labeled separately or properly. Fig(s) _____
7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)
   - ___ Hatching not indicated for sectional portions of an object. Fig(s) _____
   - ___ Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____
9. SCALE. 37 CFR 1.84(k)
   - ___ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
    - X Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Fig(s) 2A-2B
11. SHADING. 37 CFR 1.84(m)
    - ___ Solid black areas pale. Fig(s) _____
    - ___ Solid black shading not permitted. Fig(s) _____
    - ___ Shade lines, pale, rough and blurred. Fig(s) _____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
    - ___ Numbers and reference characters not plain and legible. Fig(s) _____
    - ___ Figure legends are poor. Fig(s) _____
    - ___ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1). Fig(s) _____
    - ___ English alphabet not used. 37 CFR 1.84(p)(2) Fig _____
    - ___ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____
13. LEAD LINES. 37 CFR 1.84(q)
    - ___ Lead lines cross each other. Fig(s) _____
    - ___ Lead lines missing. Fig(s) _____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
    - ___ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____
15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
    - ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____
16. CORRECTIONS. 37 CFR 1.84(w)
    - ___ Corrections not made from prior PTO-948 dated _____
17. DESIGN DRAWINGS. 37 CFR 1.152
    - ___ Surface shading shown not appropriate. Fig(s) _____
    - ___ Solid black shading not used for color contrast. Fig(s) _____

COMMENTS

REVIEWER S. Zielli DATE 12/23/99 TELEPHONE NO. 703 305-8335

ATTACHMENT TO PAPER NO. _____

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities--37 CFR 1.85

File new drawings with the changes incorporated therein. The application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application, should be placed on the back of each sheet of drawings in accordance with 37 CFR 1.84(c). Applicant may delay filing of the new drawings until receipt of the Notice of Allowability (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136. The drawing should be filed as a separate paper with a transmittal letter addressed to the Drawing Processing Branch.

2. Timing for Corrections

Applicant is required to submit acceptable corrected drawings within the three-month shortened statutory period set in the Notice of Allowability (PTOL-37). If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable corrections resubmitted within the original three-month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon a possible.

Failure to take corrective action within set (or extended) period will result in ABANDONMENT of the Application.

3. Corrections other than Informalities Noted by the Drawing Review Branch on the Form PTO-948

All changes to the drawings, other than informalities noted by the Drawing Review Branch, MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

PA-IDC #23

QUERY CONTROL FORM				RTIS USE ONLY	
Application No.	09348536	Prepared by	EWC	Tracking Number	05659482
Examiner-GAU	Cavlar 3763	Date	10-22-02	Week Date	9-30-02
		No. of queries	-1-		

JACKET			
a. Serial No.	f. Foreign Priority	k. Print Claim(s)	p. PTO-1449
b. Applicant(s)	g. Disclaimer	l. Print Fig.	q. PTOL-85b
c. Continuing Data	h. Microfiche Appendix	m. Searched Column	r. Abstract
d. PCT	i. Title	n. PTO-270/328	s. Sheets/Figs
e. Domestic Priority	j. Claims Allowed	o. PTO-892	t. Other

SPECIFICATION	MESSAGE
a. Page Missing	PTO-37 (#22) states that all certified copies have been received but none found in file.
b. Text Continuity	
c. Holes through Data	
d. Other Missing Text	
e. Illegible Text	Please advise.
f. Duplicate Text	Thank you
g. Brief Description	EWC
h. Sequence Listing	
i. Appendix	
j. Amendments	
k. Other	
CLAIMS	
a. Claim(s) Missing	
b. Improper Dependency	
c. Duplicate Numbers	
d. Incorrect Numbering	initials
e. Index Disagrees	**RESPONSE** SEE PAPER 24
f. Punctuation	
g. Amendments	
h. Bracketing	
i. Missing Text	
j. Duplicate Text	
k. Other	
	initials

E-5 (Rev. 10/01/02)

#24
DE
11/13/02

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC

405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

Serial No. : 09/348,536
Applicant : Buch-Rassmussen et al
Filing Date : 07/07/1999
Date Mailed : 11/13/2002

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 30 days from the mail date of this Notice within which to correct the informalities indicated below. A failure to reply will result in the application being ABANDONED. This period for reply is NOT extendable under 37 CFR 1.136 (a)

.TOP SHEETS OF FOREIGN PRIORITY DOCUMENTS ARE REQUIRED.

APPLICANT MUST SUPPLY TOP SHEETS WITHIN 30 DAYS OF THE MAIL DATE OF THIS NOTICE.

A copy of this notice MUST be returned with the reply. Please address response to "Box Issue Fee".

David Irvine
Data Query
Phone: Dial 1-800-877-8339; ask relay to dial 703-305-8418
Fax: 703-308-6642

FEB.11.2003 1:05PM NNNA LEGAL DEPT. NO.405 P.1/9

02-12-03
Paper # 25

novo nordisk®

NOVO NORDISK PHARMACEUTICALS, INC.

FACSIMILE TRANSMITTAL SHEET

TO: Examiner Ollie Person	FROM: Marc A. Began Esq.
COMPANY: United States Patent and Trademark Office	DATE: FEBRUARY 11, 2003
FAX NUMBER: 1 703-308-6642	TOTAL NO. OF PAGES INCLUDING COVER: 9
PHONE NUMBER:	SENDER'S PHONE NUMBER: 609-919-7829
RE: USSN: 09/348,536 Top Sheets of Foreign Priority Document PA 1998 00909 & PA 1998 01500	SENDER'S FAX NUMBER: 609-919-7741

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Dear Ms. Person:

As requested, attached herewith are the top sheets of Foreign Priority Documents PA 1998 00909 and PA 1998 01500.

Applicants have previously submitted both the Foreign Priority Documents together with a Response to File Corrected Application Papers on December 10, 2002, and have received a date stamped return postcard from the USPTO that these documents were received by the USPTO on December 17, 2002. (copies enclosed)

Best Regards,

Marc A. Began, Reg. No. 48,829

Attorney Docket No. 5637.200-US

Patent Application entitled: "Medication Delivery Device"

Applicants: Buch-Rasmussen et al.

USSN: 09/348,536

The USPTO hereby acknowledges receipt of the following:
1. Certificate of Mailing
2. Response to Notice to File Corrected Application Papers (in duplicate)
3. Copy of Notice to File Corrected Application Papers
5. Certified Copies of Priority Application(s) (2)

MCBC/RHAJ

December 10, 2002

VIA First Class Mail

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3763

Filed: July 7, 1999 Examiner: Simmons, Kevin C

Confirmation No: 5366

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Notice to File Corrected Application Papers (in duplicate)
3. Copy of Notice to File Corrected Application Papers
4. Certified copies of Priority Application(s) (2)

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on December 10, 2002.

Rashida Haji
(name of person mailing paper)

Rashida Haji
(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Corrected Application Papers dated November 13, 2002, (a copy thereof is attached hereto), Applicants enclose certified copy of Danish application nos. PA 1998 00909, filed July 8, 1998 and PA 1998 01500, filed November 17, 1998, priority of which is claimed under 35 U.S.C. 119.

Please charge any required fee, with this paper and credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: December 10, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

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Sir:

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Respectfully submitted,

Date: December 10, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

NOV 26 2002

5637.200-US

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC

405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

Serial No. : 09/348,536
Applicant : Buch-Rassmussen et al
Filing Date : 07/07/1999
Date Mailed : 11/13/2002

DOCKET (check off ✓)
ATTY:
IAB DCKT 12/2/02

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Applicant is given 30 days from the mail date of this Notice within which to correct the informalities indicated below. A failure to reply will result in the application being ABANDONED. This period for reply is NOT extendable under 37 CFR 1.136 (a)

.TOP SHEETS OF FOREIGN PRIORITY DOCUMENTS ARE REQUIRED.

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Kongeriget Danmark

Patent application No.: PA 1998 00909

Date of filing: 08 July 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

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Patent- og Varemærkestyrelsen
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TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk

PATENT- OG VAREMÆRKESTYRELSEN

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Kongeriget Danmark

Patent application No.: PA 1998 01500

Date of filing: 17 November 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

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Karin Schlichting
Head Clerk
PATENT- OG VAREMÆRKESTYRELSEN

Attorney Docket No.: 5637.200-US

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536

Group Art Unit: 3763

Filed: July 7, 1999

Examiner: Simmons, Kevin C

Confirmation No: 5366

Part of #25

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Notice to File Corrected Application Papers (in duplicate)
3. Copy of Notice to File Corrected Application Papers
4. Certified copies of Priority Application(s) (2)

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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on December 10, 2002.

Rashida Haji
(name of person mailing paper)

Rashida Haji
(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Corrected Application Papers dated November 13, 2002, (a copy thereof is attached hereto), Applicants enclose certified copy of Danish application nos. PA 1998 00909, filed July 8, 1998 and PA 1998 01500, filed November 17, 1998, priority of which is claimed under 35 U.S.C. 119.

Please charge any required fee, with this paper and credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: December 10, 2002

Marc A. Began, Reg. No. 48,829
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(609) 987-5800

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

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5637.200-US

STEVE T ZELSON
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NEW YORK NY 10174-6401

Serial No. : 09/348,536
Applicant : Buch-Rassmussen et al
Filing Date : 07/07/1999
Date Mailed : 11/13/2002

DOCKET (check off ✓)

ATTY:

MAB DCKT 12/2/02

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Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

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Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk

PATENT- OG VAREMÆRKESTYRELSEN

08/07/98 13:01 HEIDEN & HOIBERG → 43508301 Modtaget PD NR.570 03
-8 JULI 1998

The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medicaiton delivery device wherein the amount of parts of the cartridge is minimised.

Summary of the invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed as to secure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transpar-

ent, whereby the user can see whether liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged in any angle with respect to the latter coupling.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 18 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desi-

red pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. A medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. A medication delivery device according to claim 1 or 2, wherein at least one coupling means of the cartridge is an external coupling.

4. A medication delivery device according to any of the preceding claims, wherein at least one coupling means of the cartridge is a threaded coupling.

5. A medication delivery device according to any of the preceding claims, wherein the cartridge is moulded of a plastic material.

6. A medication delivery device according to any of the preceding claims, wherein the cartridge is at least partly transparent.

7. A medication delivery device according to any of the preceding claims, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

8. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprises a cartridge housing.

9. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprise a scale.

10. A medication delivery device according to any of the preceding claims, wherein the cross-section of the cartridge is non-circular.

11. A medication delivery device according to any of the preceding claims, wherein the coupling means of the cartridge are opposed each other.

12. A cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

13. A cartridge assembly according to claim 12, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

14. A cartridge assembly according to claim 12 or 13, wherein at least one coupling means of the cartridge is an external coupling.

15. A cartridge assembly according to any of the claims 12-14, wherein at least one coupling means of the cartridge is a threaded coupling.

16. A cartridge assembly according to any of the claims 12-15, wherein the cartridge is moulded of a plastic material.

17. A cartridge assembly according to any of the preceding 12-16, wherein the cartridge is at least partly transparent.

18. A cartridge assembly according to any of the claims 12-17, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

19. A cartridge assembly according to any of the claims 12-18, wherein the cartridge further comprises a cartridge housing.

20. A cartridge assembly according to any of the claims 12-19, wherein the cartridge further comprise a scale.

21. A cartridge assembly according to any of the claims 12-20, wherein the cross-section of the cartridge is non-circular.

22. A cartridge assembly according to any of the claims 12-21, wherein the coupling means of the cartridge are opposed each other.

23. A cartridge assembly according to any of the claims 12-22, which is filled with medicine.

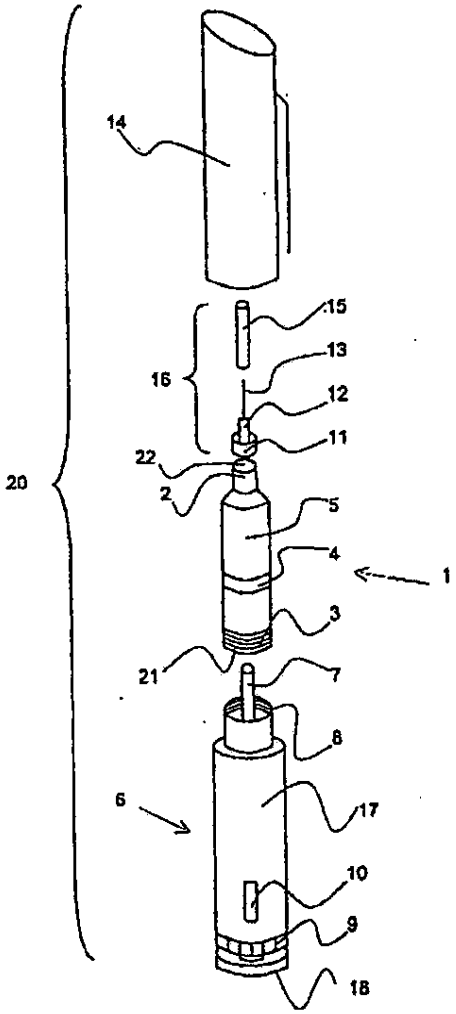

Fig. 1